REMARKS

This paper is filed in response to the Office Action dated January 7, 2009. At that time claims 1-4 and 6-20 were pending.

In the Office Action, claims 1-4 and 6-20 were rejected under 35 U.S.C. §103 over Brimhall (United States Patent No. 5,810,780), in view of Crawford (United States Patent No. 5,558,651), and Poli (United States Patent No. 5,396,925). By this paper claims 1, 2, 8, and 13 have been amended. Claims 5 and 10-12 have been cancelled. New claims 21-23 have been added. Accordingly, claims 1-4, 6-9, and 13-23 are presented for reconsideration and allowance by the Examiner.

Interview with Examiner Quynh-Nhu H. Vu

Applicants express appreciation to Examiner Vu for conducting an in-person interview with Applicant's attorney Craig Metcalf on February 25, 2009. At that time the application and outstanding Office Action were discussed. The prior art was discussed, specifically the Brimhall, Crawford, and Poli references. The differences between the prior art and the claimed invention were discussed.

Present Invention

Claim 1 defines a vascular access device having a needle having a notch, a housing, and a septum. The notch allows a small amount of blood to flow out of the needle in order to confirm that the needle is located within a blood vessel. The blood generally emerges from the needle and flows between the needle and an over-the-needle catheter. The septum stops the flow of blood out of the device. However, if the distance between the tip of the needle and the notch is greater than the length of the septum, there is a point during the withdrawal of the needle from the septum that blood can potentially flow into the tip of the needle, past the septum, and out the notch. Thus, certain claims define a "notch distance" which is the distance between the proximal end of the notch and a distal end of the opening in the distal end of the needle. This is essentially the length of the fluid channel from the needle tip to the notch. As described in the specification,

blood or other body fluid flows into the needle through the needle tip and then out of the needle through the notch.

When the needle is withdrawn, including through the defined septum, it is important that blood or other bodily fluid be contained and not leak out of the septum. In order to accomplish this result, the septum is designed to be longer than the notch distance. That is the septum is longer than the fluid path from the needle tip through the notch. In this manner there is never a point during the withdrawal of the needle where fluid is allowed to flow beyond the septum. There is not a point during the withdrawal of the needle where fluid could flow into the needle tip and then out of the notch, bypassing the septum.

In addition, the septum is equipped with a biasing element which urges the opening in the septum to a closed configuration. The septum and the biasing element are both disposed within the housing. Once the needle is fully withdrawn the septum is biased closed to prevent any fluid flow through the septum at that point. Thus, there is never uncontrolled fluid flow through the device.

Rejections Under 35 U.S.C. §103(a)

M.P.E.P. § 2141 sets forth the *Graham* factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) In addition, M.P.E.P. §§ 2141 and 2142 set forth that "the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." (Citing *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007).)

The M.P.E.P. provides several examples of rationales that can support a rejection under 35 U.S.C. § 103, namely:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

(M.P.E.P. §§ 2141 & 2143, emphasis added.) As may be seen from the emphasized portions of the above potential rationales, each rationale is dependent on showing known elements from the prior art corresponding to the limitations of the claimed invention. Each rationale therefore depends on: 1) satisfying the *Graham* enquiry of showing that the scope and content of the prior art included each limitation contained in the claimed invention, and 2) satisfactorily showing that one of ordinary skill in the art would take the art teachings to overcome the identified differences under *Graham* between the claimed invention and the individual teachings of the prior art.

Therefore, for a rejection under Section 103 to stand, it must explicitly set forth 1) factual findings showing that each claim element was known in the art at the time of the invention, and 2) factual findings showing that one of ordinary skill in the art, at the time of the invention, would have found it obvious to modify or combine the teachings to arrive at the claimed invention. (See, for example, the enumerated required articulations set forth in M.P.E.P. § 2143 for each lettered rationale.)

Applicants respectfully submit that the references in the Office Action, either alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. Applicants also respectfully submit that the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

Independent Claim 1

Claim defines a housing. Disposed within the housing is a septum through which a needle may pass. Also disposed within the housing is a biasing element which engages the septum and biases the opening in the septum to a closed position.

These features are not disclosed in the cited references and are not obvious from the references, either alone or in combination. Brimhall discloses a plug 30, through which the disclosed needle 40 may pass. However, Brimhall fails to teach or suggest a biasing element which biases the opening in the plug to a closed position.

Crawford fails to disclose a septum or plug. Crawford discloses a housing 11 which includes a pawl 30 which locks into an notch 28 in the needle 14 in order to keep the needle from being fully retracted out of the housing. *See,* Crawford Col. 5, lines 13-27. There is no teaching in Crawford of a septum having a biasing element to biasing an opening closed. The opening in the housing of Crawford is never closed.

Poli discloses a stand-alone valve which is not disposed within a housing. Poli discloses a pair of tabs 40, 42 (or 72) which can be selectively squeezed in order to open, not close, the slit. *See,* Poli, Col. 5, lines 16-23.

Therefore, none of the cited references disclose a septum in a housing, and none of the references disclose a biasing element for urging the opening in the septum into the closed position. Accordingly, claim 1 and those claims dependent therefrom, would not be obvious in view of the cited references because none of the cited reference teach the features claimed in claim 1.

Independent Claim 8

Claim 8 is not obvious for the same reasons as set forth with respect to claim 1. In addition, claim 8 provides additional features related to the biasing element and the septum. None of these features is disclosed in any of the cited references.

In addition, claim 8 defines a septum notch distance for avoiding fluid bypass through the needle tip and out the needle notch. None of the cited references disclose this feature. The

Examiner relies on Crawford. However, Crawford operates in an entirely different manner. The housing 11 of Crawford is a needle tip shielding device, not a septum device as disclosed and claimed herein. Specifically, the notch in the Crawford needle is locked in place by the pawl on the Crawford housing. Thus, Crawford fails to disclose a septum as disclosed and claimed herein.

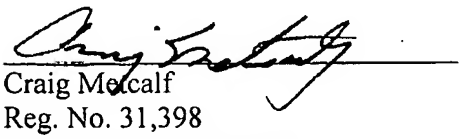
Independent Claim 13

Claim 13 provides that the biasing element is a C-shaped metal clip. There is no disclosure or suggestion in any of the cited art of this feature. Accordingly, claim 13 and its dependent claims are not obvious.

Thus, the Examiner has failed to present a prime facie case of obviousness using the cited references. The combination of references meets none of criteria for an obviousness rejection set forth above.

In view of the foregoing the Applicant respectfully submits that the claims as presented are in condition for immediate allowance. If there remain any issues that could be clarified in a telephonic conference, the examiner is respectfully requested to initiate such a conference with the undersigned.

Respectfully submitted,



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